



DEPARTMENT OF THE NAVY  
OFFICE OF THE CHIEF OF NAVAL OPERATIONS  
2000 NAVY PENTAGON  
WASHINGTON, DC 20350-2000

OPNAVINST 5530.16B  
N4  
19 Jul 2021

OPNAV INSTRUCTION 5530.16B

From: Chief of Naval Operations

Subj: MINIMUM SECURITY STANDARDS FOR SAFEGUARDING BIOLOGICAL  
SELECT AGENTS AND TOXINS

Ref: (a) DoDI 5210.88 of 26 May 2020  
(b) SECNAVINST 5510.30C

Encl: (1) Biological Select Agents and Toxins and Biological Personnel Reliability Program  
Forms  
(2) Navy Biological Personnel Reliability Program Annual Status Report

1. Purpose. To prescribe Department of Defense (DoD) policy, procedures and responsibilities for the Navy Biological Select Agents and Toxins (BSAT) Security Program per references (a) and (b). This Instruction implements DoD physical security requirements pertaining to the use, possession, storage, handling, transport, transfer, receipt or destruction of BSAT. This instruction is a complete revision and should be reviewed in its entirety.

2. Cancellation. OPNAVINST 5530.16A.

3. Background.

a. This instruction was developed in conjunction with reference (a). It includes guidance issued by DoD which was derived from the Code of Federal Regulations (CFR), United States Department of Agriculture, Department of Commerce and Department of Health and Human Services.

b. The objectives of this instruction are to:

(1) Establish policy for the minimum security of BSAT at Navy facilities by implementing all requirements prescribed in reference (a).

(2) Provide guidance and standards for Navy military, civilian and contractors with access to BSAT.

(3) Provide guidance and standards for the protection of Navy facilities housing BSAT material and for the transportation of BSAT material under Navy cognizance.

c. The term commander within this instruction includes type commanders, Fleet commanders, regional commanders, installation, ship, squadron and activity commanding officers, officers in charge and directors.

d. This instruction includes:

(1) Mandatory policies that are directive in nature and provide standards, measures or actions that are required and subject to inspection by higher headquarters and the Navy Inspector General (NAVINSGEN). An inability to meet these requirements requires a request for a waiver or exception per reference (a). Mandatory policies include the words “wills or must.”

(2) Recommendations, which, while not mandatory in nature, provide a framework that better support the mandatory policies, but are not within the purview of this instruction to mandate. Recommended procedures include the word “should.”

(3) Enabling procedures permit actions or measures within described parameters. These are not requirements, but are offered as possible actions or measures to take at the discretion of the commander. These statements include the words “may or can.”

(4) Prohibitive procedures limit an individual’s or command’s authority to take actions or implement measures. These statements include terms such as “must not” if the action is prohibited without prior authorization from an appropriate authority or “should not” if the action is advised against but left to the responsible party’s judgment.

#### 4. Scope and Applicability.

a. The policies herein pertain to preventing or mitigating hostile actions against Navy facilities with BSAT. Reference (a) addresses the threat to BSAT facilities, to include local entity command requirements and must be used to develop a comprehensive security plan.

b. Where this instruction conflicts with combatant commander security requirements, the combatant commander’s requirements take precedence. Requests for clarification should be addressed to Deputy Chief of Naval Operations, Fleet Readiness and Logistics (CNO N4).

c. This instruction applies to all Navy laboratories and facilities that furnish, have custody of or have possession of BSAT as described in reference (a), including Navy contractors and consultants that are provided BSAT by DoD.

d. Overseas facilities exempted from the provisions of 42 CFR part 73, Public Law 107-188, 9 CFR part 121 and 7 CFR part 331 due to their location will implement this instruction to the maximum extent possible. Where implementation of specific provisions is not feasible, handle per reference (a).

e. Commands wishing to establish new facilities where BSAT are used will, in addition to other approval processes and reviews, request approval during the planning stage through the appropriate chain of command. CNO N4 will be consulted regarding security requirements.

f. Navy facilities that have terminated work with BSAT will notify CNO N4 through their chain of command when BSAT are no longer maintained at the facility.

g. CNO N4 will furnish a copy of new facility approvals (prior to initial operation of the facilities) and notification of facilities that have terminated BSAT work to the Assistant Secretary of Defense (Nuclear, Chemical and Biological) (ASD (NCB)). New facility approvals regarding BSAT must be provided to CNO N4 by the echelon II command to which the BSAT facility reports.

## 5. Responsibilities.

a. CNO N4 is the focal point for the security standards of BSAT. CNO N4 is responsible for:

(1) Review and approval of all BSAT physical security waiver and exceptions. Waiver and exceptions must be forwarded via the appropriate chain of command to CNO N4. CNO N4 will forward approved waiver and exceptions per references (a) and (b). Wherever the mandatory security requirements of this instruction or reference (a) cannot be met, a waiver and exception must be submitted to the CNO N4. Only CNO N4 or its designated representative has the authority for final approval of waiver and exceptions to this instruction. The format of requests for waiver and exceptions to security standards for BSAT will be submitted immediately upon knowledge that a variance from policy exists. Endorsed waiver and exception requests will be forwarded to ASD (NCB) via the DoD executive agent for BSAT biosafety and biosecurity.

(2) Establishing overall security policy for the Navy BSAT security program.

(3) Maintaining the BSAT security program waiver and exception file for three years after the waiver and exception has been cancelled or expired.

(4) As required by reference (a), notify ASD (NCB) through the DoD Executive Agent for BSAT Biosafety and Biosecurity Programs:

(a) Before registering any new DoD BSAT entity with the Centers for Disease Control and Prevention or with United States Department of Agriculture's Animal and Plant Health Inspection Service.

(b) Following removal of such registration.

(5) Coordinate with the DoD Executive Agent for BSAT biosafety and biosecurity and approve, as part of pre-event planning, proposed public releases of information pertaining to BSAT.

(6) Comply with the secure DoD BSAT database procedures established by the ASD (NCB) and the DoD executive agent for BSAT biosafety and biosecurity.

(7) Submitting the Navy Biological Personnel Reliability Program (BPRP) annual statistical data report to ASD (NCB) and the DoD executive agent for BSAT biosafety and biosecurity by 15 February each year.

b. Deputy Chief of Naval Operations, Operations, Plans and Strategy (CNO N3/N5). As the Army is the Service assigned as the executive agent for DoD BSAT biosafety and biosecurity, the Navy watch element is responsible for reporting to the Army watch element, located in the National Military Command Center, all BSAT related incidents and mishaps reported by commander and directors of BSAT facilities.

c. Chief, Bureau of Medicine and Surgery (BUMED) is responsible for:

(1) Ensuring that commands or units under its cognizance that possess, use, produce, store, handle, transport, transfer or destroy BSAT plan and program fiscal and personnel resources necessary to meet the requirements of reference (a) and this instruction.

(2) Ensuring that the M35 (Fleet Programs), M53 chemical, biological, radiological and nuclear defense and M2 within BUMED provides a Navy representative for all Joint Service inspections of DoD BSAT laboratories.

(3) Assign a BSAT BPRP community manager responsible for training and tracking of BSAT BPRP competent medical authorities at Navy medicine readiness and training commands and Navy medicine readiness training units providing medical support to BSAT.

d. Naval Sea Systems Command (COMNAVSEASYSCOM) is responsible for:

(1) Ensuring commands or units under its cognizance possess, use, produce, store, handle, transport, transfer or destroy BSAT plan and program fiscal and personnel resources necessary to meet the requirements of reference (a) and this instruction.

e. Commanders and directors of BSAT facilities are responsible for:

(1) Development and implementation of a BSAT security program to fulfill requirements per reference (a).

- (2) Assignment in writing of a responsible official and alternate responsible official to fulfill the requirements of 7 CFR Part 331, 9 CFR Part 121, 42 CFR part 73 and reference (a).
- (3) Assignment in writing of a certifying official to fulfill the requirements of reference (a).
- (4) Ensures the duties of the reviewing official are fulfilled as required by reference (a).
- (5) Ensuring a competent medical authority is available to provide medical suitability evaluation for BPRP personnel.
- (6) Ensuring that a military, civilian or contracted drug or substance abuse testing facility is available for administration of the BSAT BPRP.
- (7) Ensure a BPRP plan is implemented to meet the requirements of reference (a).
- (8) Reports all BSAT incidents and mishaps as required by references (a) and (b).
- (9) In addition to the reporting requirement of reference (a), entities will report all incidents or mishaps that result in facility and entity closure or suspension from normal operations to the Navy component watch element located at the National Military Command Center within 24 hours of closure or suspension.
- (10) Facilities and entities will ensure that BSAT incidents and mishaps requiring Centers for Disease Control and Prevention or Animal and Plant Health Inspection Service notification are submitted within 24 hours of the incident or mishap. Written reports are required within 7 days if the BSAT incident or mishap requires a Centers for Disease Control and Prevention or Animal and Plant Health Inspection Service, Centers for Disease Control and Prevention, Form 3 notification.
- (11) All BSAT incident and mishap reports involving a theft, loss or release as defined in section 1528 of title 50 U.S. Code will include the information annotated in subparagraphs 5e(11)(a) through 5e(11)(e).
  - (a) The name of the agent or toxin and any identifying information, including the strain or other relevant characterization information.
  - (b) An estimate of the quantity of the agent or toxin stolen, lost or released.
  - (c) The location or facility from which the theft, loss or release occurred.
  - (d) In the case of a release, any hazards posed by the release and the number of individuals potentially exposed to the agent or toxin.

(e) Actions taken to respond to the theft, loss or release.

(12) Submit annual BPRP statistical data per reference (a), concerning the BPRP to Deputy Chief of Naval Operations, Fleet Readiness and Logistic, Shore Readiness (CNO N4) for the preceding calendar year, ending 31 December. Annual status reports must be received by 15 January.

6. Implementation. BSAT facilities will ensure compliance to this instruction upon issuance.

7. Records Management.

a. Records created as a result of this notice, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the Department of the Navy Directorate for Administration, Logistics, and Operations, Directives and Records Management Division portal page at

<https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx>.

b. For questions concerning the management of records related to this change transmittal or the records disposition schedules, please contact the local records manager or the Department of the Navy Directorate for Administration, Logistics, and Operations, Directives and Records Management Division program office.

8. Review and Effective Date. Per OPNAVINST 5215.17A, CNO N4 will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency and consistency with Federal, DoD, Secretary of the Navy and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV Manual 5215.1 of May 2016.



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(Fleet Readiness and Logistics)

Releasability and distribution:

This instruction is cleared for public release and is available electronically only via Department of the Navy Issuances Web site, <https://www.secnav.navy.mil/doni/default.aspx>.

BIOLOGICAL SELECT AGENTS AND TOXINS AND BIOLOGICAL PERSONNEL  
RELIABILITY PROGRAM FORMS

1. Screening and Evaluation Record. A screening and evaluation record will be completed for each individual screened and evaluated for the BPRP.
2. BPRP Annual Report Form. Each BSAT facility will submit an annual status report to CNO N4 for the preceding calendar year, ending 31 December.
  - a. Annual status reports will be received by CNO N4 no later than 15 January. BSAT facilities should verify receipt by phone call or e-mail.
  - b. The annual status report will be completed per reference (a) and will include BPRP certification, number of personnel certified, denied certification, terminated administratively and permanent decertification statistics by facility and category of personnel. Cover letters should include point of contact information for the report.
  - c. Since permanent decertification's generally include more than one issue, the reason for permanent decertification action should be accounted for only once under the predominant issue.

NAVY BIOLOGICAL PERSONNEL RELIABILITY PROGRAM ANNUAL STATUS  
REPORT

Calendar Year Ending December 31, 20\_\_

DON BSAT Facility:\_\_\_\_\_

	Active Duty Military	Civilians (US)	Civilians (LN)	Contractors (US)	Contractors (LN)	Total
Total number of BPRP certified personnel						
Total number of permanent decertifications						
Total number denied certification						
Total number terminated administratively						

*Reason for permanent decertification*

Alcohol-related						
Drug-related						
Inability to obtain or revocation of security clearance eligibility						
Inability to meet safety requirements						
Suicide attempt or threat						
Other significant medical condition						
Negligence or delinquency in performance of duty						
Conviction of a serious incident						
Poor attitude or lack of motivation						



Aggressive or threatening behavior						
Attempting to conceal PDI						
Other inappropriate attitude or behavior						
Total number of requalifications						

Remarks or additional comments: